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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,562	01/26/2001	William J. Curatolo	PC9674AJTJ	8513

7590

06/18/2002

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/18/2002 18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/770,562

Applicant(s)

CURATOLO ET AL.

Examiner

Blessing M. Fubara

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,7,10,11,13,15,17,19-21,23-27,36 and 38 is/are rejected.
- 7) ☐ Claim(s) 2,3,6,9,12,14,16,18,22,28-35 and 37 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8 & 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Examiner acknowledges receipt of paper numbers 6 and 7 filed 03/19/02 and paper numbers 8 and 9 filed 04/02/02 and 04/03/02 respectively. Claims 1-38 are pending.

#### ***Claim Rejections - 35 USC § 112***

1. The rejection of claims 1-38 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in light of the amendments and arguments presented in paper number 7 filed 03/19/02.

#### ***Claim Rejections - 35 USC § 102***

2. Claims 1, 4, 5, 7, 10, 11, 13, 15 and 17 remain rejected under 35 U.S.C. 102(b) as being anticipated by JP (Kokai) No. 57-176907.
3. Claims 1, 4, 5, 7, 10, 11, 13, 15, 17 and 22-26 remain rejected under 35 U.S.C. 102(b) as being anticipated by JP (Kokai) No. 2-15027.
4. Claims 1, 7, 11, 15, 36 and 38 remain rejected under 35 U.S.C. 102(b) as being anticipated by Nakamichi et al. (US 5,456,923).

#### ***Response to Arguments***

Applicants traversed the rejection above for the following reasons:

Applicants state that none of the references cited above discloses a spray dried dispersion of HPMCAS and a sparingly soluble drug. Specifically, applicants state that in JP 57-176907, example 5, teaches HPMCAS but the drying process is by solvent evaporation and not by spray drying, while examples 1-4 teaches spray drying, the polymer is not HPMCAS, and examples 6-12 uses polymers other than HPMCAS and

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does not spray dry. Applicants' argument is specifically related to spray drying, which applicants allege is not the process in the cited references. To this effect applicants submitted a 132 declaration to point out the differences between the applicants spray dried composition and those of the prior art.

5. However, applicant's arguments filed 03/19/02 have been fully considered but they are not persuasive. It is not required that all the examples teach HMPCAS and it is sufficient that an exemplification is provided and the drying process is not critical. Contrary to applicants' contention, JP 2-15027 teaches HPMCAS on page 2, line 6 from the bottom of the translation. It is maintained that the process of preparing a composition is not critical in a composition claim. Although, applicants desired to specifically show that the spray dried solid dispersion of the application has unexpected result over the solids of the prior art, **the scope of the claims is not commensurate with a showing in the declaration.**

The claims in the application read on solid compositions comprising a sparingly water-soluble drug and hydroxypropyl methyl cellulose acetate succinate. The solid composition is prepared by spray drying.

JP (Kokai) No. 57-176907 discloses a solid preparation comprising 4-(cis-p-methan-8-yloxy) benzanilide (poor water-soluble drug) and hydroxypropyl methyl cellulose acetate succinate. The preparation is spray dried or vacuum dried. See pages 2-7 of translation. However, the process of preparing a composition is not critical in a composition claim. What is required is for the prior art to teach the composition and the process of making the composition does not distinguish over the prior art. Thus, the teachings of the prior art read on the claims.

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JP (Kokai) No. 2-15027 teaches a solid preparation comprising probucol (poor water-soluble drug) and hydroxypropyl methyl cellulose acetate succinate polymer and the mean particle diameter is not more than 10  $\mu\text{m}$  (see pages 2-8 of translation). The process of preparing a composition is not critical in a composition claim. A mean particle diameter of 10  $\mu\text{m}$  is less than 100  $\mu\text{m}$ . It is only required that the prior art to teach the composition and the process of making the composition does not distinguish over the prior art. Thus, the teachings of the prior art read on the claims.

Nakamichi, in (US 5,456,923), teaches a solid composition comprising a drug and hydroxypropyl methyl cellulose acetate succinate (abstract, column 1, lines 59-63, column 2, lines 43-47 and column 6, lines 11-19). Some of the drugs applicable in the invention are theophylline, phenytoin and enalapril (column 4, lines 26-28, column 5, lines 14-16 and lines 47-49). The process of preparing a composition is not critical in a composition claim. What is required is for the prior art to teach the composition and the process of making the composition does not distinguish over the prior art. Thus, the teachings of the prior art read on the claims.

Applicants failed to address the rejection under 35 USC 103 and the rejection under 35 USC § 103 is reiterated below.

***Claim Rejections - 35 USC § 103***

6. Claims 19-21 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP (Kokai) No. 57-176907.

The teachings of the prior art are discussed above. The JP (Kokai) No. 57-176907 reference is silent on the size of the particle. However, the process of the prior art would yield particles that one having ordinary skill in the art would determine. Therefore, it would have

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been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of JP (Kokai) No. 57-176907. One having ordinary skill in the art would have been motivated to prepare the composition of JP (Kokai) No. 57-176907. One having ordinary skill in the art would know routine experimental process of measuring particle sizes. Applicants provided no indication of the concentration of drug or solvent that would yield particle size of less than 100  $\mu\text{m}$  in diameter. In the absence of a showing, the particle size does not distinguish the invention over the prior art.

7. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP (Kokai) No. 2-15027.

The teachings of JP (Kokai) No. 2-15027 are discussed above. However, the prior art is silent on the ratio drug to hydroxypropyl methyl cellulose acetate succinate. Although, the prior art is silent, it is obvious that the composition comprises a certain amount of drug and a certain amount of the polymer. The prior art teaches 10 parts of the drug probucol to 13 part of polymer that is not hydroxypropyl methyl cellulose acetate succinate (examples 1-2). The ratio appears to be an optimization of the composition. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of JP (Kokai) No. 2-15027. One having ordinary skill in the art would have been motivated to prepare the composition of the prior art and to optimize the ratio of the drug to the polymer as desired for the composition.

8. Claims 2, 3, 6, 8, 9, 12, 14, 16, 18, 22, 28-35 and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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9. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

*Blessing Fubara*

*THURMAN K. PAGE*  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600